

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF ALABAMA  
NORTHERN DIVISION

RECEIVED

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U.S. DISTRICT COURT  
MIDDLE DISTRICT ALA

ROBERT BLANKENSHIP,

Plaintiff,

v.

PFIZER, INC., BOEHRINGER  
INGELHEIM PHARMACEUTICALS,  
INC., DAVID ROHLING, KMART OF  
MICHIGAN, INC., ART REDDING,  
KELLI STRANGE, et al.,

Defendants.

CIVIL ACTION NO.

2:06 CV 648 -

ANSWER AND DEFENSE OF  
BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC. TO  
PLAINTIFF'S COMPLAINT;  
AND REQUEST FOR JURY  
TRIAL

Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), for its Answer to  
Plaintiffs' Complaint ("Plaintiff's Complaint"), states as follows:

**Statement of the Parties**

1. BIPI is without knowledge or information sufficient to form a belief as to the truth  
of the allegations contained in Paragraph 1 of plaintiff's Complaint relating to plaintiff's  
residence or age and therefore leaves plaintiff to his proofs.

2. The allegations contained in Paragraph 2 of plaintiff's Complaint do not relate to  
and are not directed at BIPI; therefore no response is required.

3. BIPI admits that it is a corporation organized under the laws of the state of  
Delaware, and admits that it is authorized to do business in Alabama. BIPI further admits that it  
is involved in marketing and distributing Mirapex. Without knowing the specific time period to  
which paragraph 3 is directed, BIPI is without knowledge sufficient to form a belief as to

whether BIPI was doing business through an agent in Barbour County, Alabama during that time.

4. The allegations contained in Paragraph 4 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

5. The allegations contained in Paragraph 5 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

6. The allegations contained in Paragraph 6 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

7. The allegations contained in Paragraph 7 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

8. The allegations contained in Paragraph 8 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

9. The allegations contained in Paragraph 9 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

10. The allegations contained in Paragraph 10 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

11. The allegations contained in Paragraph 11 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

12. The allegations contained in Paragraph 12 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

13. The allegations contained in Paragraph 13 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

**Statement of the Facts**

14. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 14 of plaintiff's Complaint and therefore must deny the same.

15. BIPI denies the allegations contained in paragraph 15, except that BIPI admits that Mirapex is the trade name for Pramipexole dihydrochloride and admits that Mirapex is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's Disease.

16. BIPI denies the allegations contained in Paragraph 16, except BIPI admits that it advertised and marketed Mirapex as a safe and effective medication for Parkinson's Disease treatment.

17. BIPI admits that Mirapex is within the class of drugs known as dopamine agonists. BIPI further states that the characteristics of Parkinson's Disease and the pharmacologic effects of dopamine agonists are described in the peer reviewed medical literature.

18. BIPI denies the allegations contained in Paragraph 18.

19. BIPI denies the allegations contained in Paragraph 19, except BIPI admits that it published materials used to market Mirapex to physicians.

20. BIPI denies the allegations contained in Paragraph 20.

21. BIPI denies the allegations contained in Paragraph 21.

22. BIPI denies the allegations contained in Paragraph 22.

23. BIPI denies the allegations contained in Paragraph 23.

24. BIPI denies the allegations contained in Paragraph 24.

25. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25 of plaintiff's Complaint and therefore must deny the same.

26. BIPI is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of plaintiff's Complaint and therefore must deny the same.

**COUNT ONE**

**(Alabama Extended Manufacturer's Liability Doctrine [AEMLD])**

27. BIPI incorporates by reference its responses to the above paragraphs as though fully set forth herein.

28. BIPI denies the allegations contained in Paragraph 28.

29. BIPI denies the allegations contained in Paragraph 29.

30. BIPI denies the allegations contained in Paragraph 30.

31. BIPI denies the allegations contained in Paragraph 31.

32. BIPI denies the allegations contained in Paragraph 32.

In response to the unnumbered paragraph beginning “WHEREFORE, ...” BIPI denies that plaintiff is entitled to any relief whatsoever.

**COUNT TWO**

**(Negligence)**

33. BIPI incorporates by reference its responses to the above paragraphs as though fully set forth herein.

34. BIPI denies the allegations contained in Paragraph 34.

35. The allegations contained in Paragraph 35 of plaintiff’s Complaint do not relate to and are not directed at BIPI; therefore no response is required.

36. The allegations contained in Paragraph 36 of plaintiff’s Complaint do not relate to and are not directed at BIPI; therefore no response is required.

37. BIPI denies the allegations contained in Paragraph 37.

In response to the unnumbered paragraph beginning “WHEREFORE, ...” BIPI denies that plaintiff is entitled to any relief whatsoever.

**COUNT THREE**

**(Wantonness)**

38. BIPI incorporates by reference its responses to the above paragraphs as though fully set forth herein.

39. BIPI denies the allegations contained in Paragraph 39.

40. The allegations contained in Paragraph 40 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

41. The allegations contained in Paragraph 41 of plaintiff's Complaint do not relate to and are not directed at BIPI; therefore no response is required.

42. BIPI denies the allegations contained in Paragraph 42.

In response to the unnumbered paragraph beginning "WHEREFORE, ..." BIPI denies that plaintiff is entitled to any relief whatsoever.

#### **COUNT FOUR**

##### **(Fraud)**

43. BIPI incorporates by reference its responses to the above paragraphs as though fully set forth herein.

44. BIPI denies the allegations contained in Paragraph 44.

45. BIPI denies the allegations contained in Paragraph 45, which state legal conclusions. To the extent that any response is required, BIPI states that it complied with its legal obligations.

46. BIPI denies the allegations contained in Paragraph 46, which state legal conclusions. To the extent that any response is required, BIPI states that it complied with its legal obligations.

47. BIPI denies the allegations contained in Paragraph 47.

48. BIPI denies the allegations contained in Paragraph 48.

In response to the unnumbered paragraph beginning “WHEREFORE, ...” BIPI denies that plaintiff is entitled to any relief whatsoever.

### **AFFIRMATIVE DEFENSES**

#### **FIRST SEPARATE DEFENSE**

49. The Complaint fails to state a claim upon which relief can be granted.

#### **SECOND SEPARATE DEFENSE**

50. Plaintiff’s claims are pre-empted in whole or in part by the Federal Food, Drug & Cosmetic Act, the supremacy clause of Article VI of the United States Constitution, and/or federal and/or state laws and regulations governing the labeling, advertising, and sale of prescription pharmaceutical products.

### **THIRD SEPARATE DEFENSE**

51. Plaintiff's claims are barred, in whole or in part, by the defenses set forth in comment k of the Restatement (Second) of Torts §402A and/or similar provisions of the Restatement (Third) of Torts including but not limited to §6 thereof.

### **FOURTH SEPARATE DEFENSE**

52. Plaintiff's claims are barred, in whole or in part, by the defenses set forth in comment j of the Restatement (Second) of Torts §402A and/or similar provisions of the Restatement (Third) of Torts including but not limited to §6 thereof.

### **FIFTH SEPARATE DEFENSE**

53. Plaintiff's alleged injuries or damages, if any, were caused, in whole or in part, by the operation of nature or an act of God and are not the result of any act or omission of BIPI.

### **SIXTH SEPARATE DEFENSE**

54. Plaintiff may not recover from BIPI because plaintiff's claims are premised on unreliable, unproven, and unsupported scientific theories subject to substantial debate and disagreement within the scientific and medical communities.

### **SEVENTH SEPARATE DEFENSE**

55. Some or all of plaintiff's alleged injuries were caused or aggravated by plaintiff's pre-existing medical or psychological condition or exposure to other substances utilized throughout his lifetime, or plaintiff's unusual susceptibility to injury.



### **EIGHTH AFFIRMATIVE DEFENSE**

56. BIPI provided complete and adequate warnings concerning Mirapex to plaintiff's prescribing physicians. Therefore, any claims by plaintiff for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.

### **NINTH SEPARATE DEFENSE**

57. Plaintiff's alleged damages and injuries were directly and proximately caused by the superseding intervening acts and conduct of others over whom BIPI had no control, thereby precluding plaintiff from any recovery from BIPI.

### **TENTH SEPARATE DEFENSE**

58. Plaintiff had full knowledge of the risks and possible adverse effects pertaining to the use of the prescription medical product described in the Complaint, and all or part of the alleged injuries, damages, and/or losses, if any, sustained by plaintiff arose from and were caused by risks of which the plaintiff was so aware, and such risks were accepted and assumed by the plaintiff, and for that reason any recovery against BIPI should be diminished, reduced, offset, or barred in accordance with the principles of assumption of risk and/or informed consent.

### **ELEVENTH SEPARATE DEFENSE**

59. The alleged injuries and damages sustained by plaintiff were the result of plaintiff's own negligence and/or contributory negligence and, accordingly, plaintiff is barred from recovery or limited to recovery.

### **TWELFTH SEPARATE DEFENSE**

60. Plaintiff's claims for breach of warranty are barred by BIPI's disclaimers of warranties and limitations of remedies.

**THIRTEENTH SEPARATE DEFENSE**

61. Plaintiff's claims for breach of warranty are barred by lack of privity of contract between plaintiff and BIPI, and/or the disclaimer of warranties and limitations of remedies, and/or the failure of the plaintiff to provide BIPI with notice of an alleged breach.

**FOURTEENTH SEPARATE DEFENSE**

62. Any product manufactured and/or sold and/or distributed by BIPI which was or may have been furnished to plaintiff was subjected to a substantial change in its condition after it left the control of BIPI. It is further averred that this change was unforeseeable.

**FIFTEENTH SEPARATE DEFENSE**

63. Any product manufactured and/or sold and/or distributed by BIPI which was or may have been furnished to plaintiff, was furnished with adequate and appropriate warnings.

**SIXTEENTH SEPARATE DEFENSE**

64. Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations and/or statute of repose.

**SEVENTEENTH SEPARATE DEFENSE**

65. Plaintiff's claims are barred, in whole or in part, because there is no private right of action under the Federal Food, Drug & Cosmetic Act.

**EIGHTEENTH SEPARATE DEFENSE**

66. BIPI violated no duty or obligation owed to plaintiff.

**TWENTIETH SEPARATE DEFENSE**

67. Plaintiff's alleged injuries and damages were not caused by any product manufactured, distributed, or sold by BIPI but by some other product, process, occurrence, event, or service over which BIPI exercised no control or right of control.

**TWENTY-FIRST SEPARATE DEFENSE**

68. Plaintiff is barred from recovery because the prescription medical product alleged to have caused plaintiff's injuries was altered from its original condition and/or combined with other prescription products or other products after leaving BIPI's control.

**TWENTY-SECOND SEPARATE DEFENSE**

69. Plaintiff failed to mitigate his damages, if any, and, as a result, any recovery against BIPI should be barred, reduced, or offset accordingly.

**TWENTY-THIRD SEPARATE DEFENSE**

70. Any alleged danger associated with the use of the prescription medical product that caused plaintiff's alleged injuries was open and obvious and plaintiff is therefore barred from recovery.

**TWENTY-FOURTH SEPARATE DEFENSE**

71. Plaintiff's claims are barred, in whole or in part, by the doctrine of unclean hands, laches, waiver and/or estoppel.

**TWENTY-FIFTH SEPARATE DEFENSE**

72. Each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified, in whole or in part, by collateral sources and must be offset by those sources.

**TWENTY-SIXTH SEPARATE DEFENSE**

73. BIPI is entitled to the benefit of all defenses and presumptions contained in, or arising from, any product liability act and/or Uniform Commercial Code enacted by the state whose substantive law controls in this action.

**TWENTY-SEVENTH SEPARATE DEFENSE**

74. If any product manufactured, distributed, or sold by BIPI caused plaintiff's alleged injuries, then such harm and/or damage was the sole proximate result of misuse, modification, and/or abuse of the product in a manner neither intended nor foreseen by BIPI.

**TWENTY-EIGHTH SEPARATE DEFENSE**

75. Any and all warnings and information pertaining to products designed, manufactured and/or distributed and/or sold by BIPI were at all times relevant to the Complaint in conformity with governmental requirements mandating the content and distribution of such warnings and information.

**TWENTY-NINTH SEPARATE DEFENSE**

76. Any product manufactured, labeled, or distributed by BIPI complied with all applicable industry and governmental standards and regulations and reflected the current state of the art at the time they were manufactured.

### **THIRTIETH SEPARATE DEFENSE**

77. The product of which plaintiff complains has certain unavoidable, inherent characteristics which cannot be obviated under the state of scientific knowledge existing at the time such product was manufactured. If plaintiff had sustained any injuries as a result of the use of or exposure to the product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which BIPI cannot be held responsible.

### **THIRTY-FIRST SEPARATE DEFENSE**

78. The product of which plaintiff complains has certain unavoidable, inherent characteristics. While denying that such characteristics are dangerous or defective, under the state of scientific knowledge at the time such product was manufactured, a practical and technically feasible alternative design that would have prevented the alleged harm was not available without substantially impairing the usefulness or intended purpose of the product. Consequently, BIPI did not act unreasonably in introducing the product into trade or commerce.

### **THIRTY-SECOND SEPARATE DEFENSE**

79. Plaintiff has failed to join parties in whose absence complete relief cannot be afforded.

### **THIRTY-THIRD SEPARATE DEFENSE**

80. If plaintiff sustained the injuries alleged in the Complaint, which is denied, there was an intervening, superseding cause or causes leading to the alleged injuries; and therefore, any action of the part of BIPI was not the proximate and/or competent producing cause of the alleged injuries.

**THIRTY-FOURTH SEPARATE DEFENSE**

81. Plaintiff's exposure, if any, to any product for which BIPI may be legally responsible was de minimis, so that BIPI's product, if any, was not a substantial contributing factor to any condition for which plaintiff seeks recovery in this action.

**THIRTY-FIFTH SEPARATE DEFENSE**

82. This Court lacks personal jurisdiction over BIPI.

**THIRTY-SIXTH SEPARATE DEFENSE**

83. Venue is improper and/or would be more convenient in another court.

**THIRTY-SEVENTH SEPARATE DEFENSE**

84. Plaintiff's complaint should be dismissed on grounds of forum non conveniens.

**THIRTY-EIGHTH SEPARATE DEFENSE**

85. BIPI's products and/or actions were neither the cause in fact nor the proximate cause of plaintiff's injury, if any.

**THIRTY-NINTH SEPARATE DEFENSE**

86. BIPI made no representations which induced, or otherwise were a factor in causing plaintiff to purchase or use any product manufactured or supplied by BIPI.

**FORTIETH SEPARATE DEFENSE**

87. Plaintiff has failed to plead fraud or other intentional misconduct with sufficient particularity.

**FORTY-FIRST SEPARATE DEFENSE**

88. Plaintiff's alleged gambling losses are due to factors other than the alleged ingestion of Mirapex including chance, luck and other characteristics inherent in gambling activities.

**FORTY-SECOND SEPARATE DEFENSE**

89. Plaintiff's effort to attribute his gambling losses solely to ingestion of Mirapex is inherently speculative and unsupportable by admissible evidence.

**FORTY-THIRD SEPARATE DEFENSE**

90. Plaintiff's effort to recover for gambling losses is void as against public policy.

**FORTY-FOURTH SEPARATE DEFENSE**

91. BIPI incorporates by reference the affirmative defenses set forth by any other defendant in this action to the extent consistent with BIPI's Answer as though fully set forth herein, and BIPI hereby gives notice of its intention to rely upon such other affirmative defenses as may become available or apparent during the course of discovery and reserves the right to amend its Answer to assert such defenses.

**FORTY-FIFTH SEPARATE DEFENSE**

92. To the extent not incorporated above, Defendant raises all affirmative defenses available under the law of the forum in which the alleged cause of action arose.

**FORTY-SIXTH SEPARATE DEFENSE**

93. The conduct of BIPI and all activities with respect to the subject product have been and are under the supervision of the FDA. Accordingly, this action, including any claims

for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

**FORTY-SEVENTH SEPARATE DEFENSE**

94. The claims asserted in the plaintiff's Complaint are barred, in whole or in part, because the utility of Mirapex outweighs the alleged risk.

**FORTY-EIGHTH SEPARATE DEFENSE**

95. The claims asserted in plaintiff's Complaint are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the product, were not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the Constitution of the United States.

**FORTY-NINTH SEPARATE DEFENSE**

96. The claims asserted in plaintiff's Complaint are barred, in whole or in part, because the product provides net benefits for a class of patients within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

**FIFTIETH SEPARATE DEFENSE**

97. Plaintiff's claims are barred because, based on the state of scientific, medical and technical knowledge at the time Mirapex was marketed, Mirapex was reasonably safe for its normal and foreseeable use.

**FIFTY-FIRST SEPARATE DEFENSE**

98. The Complaint's prayers for damages are barred because plaintiff's damages, if any, are speculative, uncertain, and incapable of being ascertained.



**FIFTY-SECOND SEPARATE DEFENSE**

99. BIPI denies, to the extent the actions alleged may have occurred, that any entity engaging in the activities alleged was acting as the agent or servant of BIPI, or at the instruction or subject to the control of BIPI with regard to any of the actions described in the Complaint; thus, BIPI is not liable for any acts or omissions of such third parties as a matter of law.

**FIFTY-THIRD SEPARATE DEFENSE**

100. BIPI avers that it did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

**FIFTY-FOURTH SEPARATE DEFENSE**

101. An award of mental anguish or emotional distress damages in this case will violate BIPI's Due Process and Equal Protection rights guaranteed by the Alabama Constitution and the United States Constitution because Alabama juries are not given any rules, standards, or guidelines upon which to rely in calculating mental anguish or emotional distress damage awards.

**FIFTY-FIFTH SEPARATE DEFENSE**

102. To award plaintiff damages for alleged mental anguish or emotional distress in the absence of any standards for the determination of mental anguish or emotional distress and/or the absence of any requirement for corroborating or objective evidence of mental anguish or emotional distress makes such an award tantamount to punitive damages. As such, BIPI avers that such an award in this case would violate the safeguards provided to BIPI under both the Alabama Constitution and the United States Constitution.

**FIFTY-SIXTH SEPARATE DEFENSE**

103. BIPI pleads the general issue.

**FIFTY-SEVENTH SEPARATE DEFENSE**

104. Because of the lack of clear standards, any imposition of punitive damages against BIPI is unconstitutionally vague and/or overbroad.

**FIFTH-EIGHTH SEPARATE DEFENSE**

105. No act or omission of BIPI was malicious, willful, wanton, reckless, grossly negligent or intentional and, therefore, any award of punitive damages is barred.

**FIFTY-NINTH SEPARATE DEFENSE**

106. No punitive damages are warranted or allowable that would exceed comparable maximums established for criminal fines.

**SIXTIETH SEPARATE DEFENSE**

107. Any award of punitive damages is barred or limited by *Ala. Code* §§ 6-11-20 through 6-11-27 (Supp. 2002).

**SIXTY-FIRST SEPARATE DEFENSE**

108. Any claim for punitive damages, on its face and/or as applied in this case, is in violation of Article 1, Sections 1, 2, 6, 11, 13, 15, 27, and 35 of the Constitution of Alabama of 1901, and is improper under the common law and public policies of the State of Alabama and under applicable court rules and statutes for the following reasons, jointly and separately:

- (a) There are no standards provided by Alabama law for the imposition of punitive damages, and therefore, BIPI has not been put on notice and

given the opportunity to anticipate punitive liability and/or the potential size of the award and to modify or conform its conduct accordingly;

- (b) The procedures to be followed would permit an award of punitive damages against BIPI upon the satisfaction of a burden of persuasion (standard of proof) less than that applicable to the imposition of criminal sanctions for equal culpability;
- (c) The procedures to be followed could permit the award of multiple punitive damages for the same act or omission;
- (d) There are no provisions or standards for clear and consistent appellate review of any award of punitive damages against BIPI under present Alabama law;
- (e) The standards of conduct upon which punitive damages are sought against BIPI are vague and ambiguous;
- (f) The procedures used by courts under Alabama law and the guidelines given by the jurors, jointly and severally, are vague and ambiguous;
- (g) The procedures used by courts under Alabama law and guidelines given to jurors, jointly and separately, are vague and ambiguous and, thus, impermissibly allow jurors broad, unlimited, and undefined power to make determinations on their notions of what the law should be instead of what it is;
- (h) The procedures under which punitive damages are awarded and the instructions used under Alabama law, jointly and separately, are vague and ambiguous and, thus, fail to eliminate the effects of, and to guard against, impermissible juror passion;
- (i) Present Alabama law does not provide for sufficiently objective and specific standards to be used by the jury in its deliberations on whether to award punitive damages and, if so, on the amount to be awarded;
- (j) Present Alabama law does not provide a meaningful opportunity for challenging the rational basis for, and any excessiveness of, any award of punitive damages;
- (k) Present Alabama law does not provide for adequate and independent review by the trial court and the appellate court of the imposition of punitive damages by a jury or of the amount of any punitive damage awarded by a jury;

- (l) Present Alabama procedures fail to provide a constitutionally reasonable limit on the amount of any punitive damage award against BIPI;
- (m) Present Alabama procedures may permit the admission of evidence relative to punitive damages in the same proceeding during which liability is determined;
- (n) Present Alabama procedures permit the imposition of joint and several judgments against multiple co-defendants for different acts of degrees of wrongdoing or culpability;
- (o) An award of punitive damages would compensate plaintiffs for elements of damage not otherwise recognized by Alabama law.

Moreover, any award of punitive damages in the circumstances of this case would violate BIPI's due process rights as embraced by the due process clause of Article 1, Section 6 and/or 13 and/or 22 of the Alabama Constitution, jointly and separately, as such award would constitute a deprivation of property without due process of law for the following reasons as separately stated herein:

- (a) There is no rational relationship between the punitive damage awards in Alabama and the wrongfulness of a defendant's conduct and/or the compensatory damages awarded.
- (b) No rational relationship exists between the extent of punitive damages and legitimate interests to be advanced by the State of Alabama.
- (c) An award of punitive damages in this case would be penal in nature and thus, would be violative of BIPI's constitutional rights under the United States Constitution and/or the Alabama Constitution unless BIPI is granted the procedural safeguards afforded criminal defendants including but not limited to constitutional safeguards against self-incrimination and a heightened standard of proof beyond a reasonable doubt.
- (d) The award of punitive damages on the basis of vicarious liability for the conduct of others violates BIPI's constitutional rights.

In addition, any award of punitive damages in this case would violate BIPI's rights under Article 1, Section 22 of the Alabama Constitution in that it would impair the contractual obligations of parties to this litigation.

## SIXTY-SECOND SEPARATE DEFENSE

109. Plaintiff's claims for punitive damages are in contravention of BIPI's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause in the Fifth Amendment to the United States Constitution; the Commerce Clause of the United States Constitution; the Contracts Clause of the United States Constitution; and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution, in the circumstances of this litigation, including, but not limited to:

- (a) imposition of punitive damages by a jury which
  - (1) is not provided with standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award;
  - (2) is not adequately and clearly instructed on the limits on punitive damages imposed by the principles of deterrence and punishment;
  - (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award thereof, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of BIPI;
  - (4) is permitted to award punitive damages under a standard for determining liability for such damages which is vague and arbitrary and does not define with sufficient clarity the conduct or mental state which makes punitive damages permissible; and
  - (5) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards;
- (b) imposition of such punitive damages, and determination of the amount of an award thereof, where applicable state law is impermissibly vague, imprecise, or inconsistent;
- (c) imposition of such punitive damages, and determination of the amount of an award thereof, without bifurcating the trial and trying all punitive

damages issues only if and after the liability of defendants has been found on the merits;

- (d) imposition of such punitive damages, and determination of the amount of an award thereof, based on anything other than BIPI's conduct in connection with the sale of the product alleged in this litigation, or in any other way subjecting BIPI to impermissible multiple punishment for the same alleged wrong.

#### **SIXTY-THIRD SEPARATE DEFENSE**

110. With respect to any demand by plaintiff for punitive damages, BIPI specifically incorporates by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), and *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).

#### **SIXTY-FOURTH SEPARATE DEFENSE**

111. To the extent that any demand by plaintiff for punitive damages may result in multiple punitive damage awards being assessed for the same act or omission against BIPI, this award contravenes BIPI's right to due process under the Due Process Clause of Article 1, Section 13 of the Alabama Constitution. In addition, such awards would infringe upon BIPI's rights against double jeopardy insured by the Fifth Amendment of the United States Constitution and/or Article 1, Section 9 of the Alabama Constitution.

#### **SIXTY-FIFTH SEPARATE DEFENSE**

112. The procedures pursuant to which punitive damages are awarded expose civil defendants to the risk of indefinable, unlimited liability unrelated to actual loss, if any, caused by

their conduct, creating a chilling effect on the defendants' exercise of the right to a judicial resolution of this dispute.

#### **SIXTY-SIXTH SEPARATE DEFENSE**

113. To the extent plaintiff has suffered no physical injury, § 6-11-21 of the *Code of Alabama* bars plaintiff's claim for punitive damages insofar as said claim exceeds the greater of three times plaintiff's compensatory damages or \$500,000, which the Alabama Legislature has established as the outer limit of reasonableness for awards of punitive damages as a matter of public policy in this state. To the extent plaintiff does claim that he has suffered physical injury, § 6-11-21 of the *Code of Alabama* bars plaintiff's claim for punitive damages insofar as said claim exceeds the greater of three times plaintiff's compensatory damages or \$1,500,000, which the Alabama Legislature has established as the outer limit of reasonableness for awards of punitive damages as a matter of public policy in this state.

#### **SIXTY-SEVENTH SEPARATE DEFENSE**

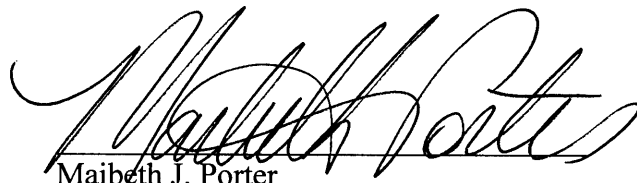
114. Old Code Section 6-11-21 of the *Code of Alabama* bars plaintiff's claims for punitive damages to the extent that it exceeds the amount of \$250,000.00, which the Alabama Legislature has established as the outer limit of reasonableness for awards of punitive damages as a matter of public policy in this state. The Alabama Supreme Court acted beyond its scope of authority and violated the separation of powers clause of the United States Constitution and/or the Alabama Constitution in striking down this legislative mandate, and therefore, its action was unconstitutional and without effect. Allowing an award in excess of this legislative cap directly contravenes the express public policy of the State of Alabama.

**WHEREFORE**, having fully answered the allegations of plaintiff's Complaint, BIPI respectfully requests judgment as follows:

1. That this Court dismiss plaintiff's causes of action against it,
2. To award BIPI its costs and expenses herein incurred and expended,
3. And for such other and further relief as this Court deems just and proper.

**JURY DEMAND**

BIPI hereby demands a trial by jury on all issues so triable.



Maibeth J. Porter  
Alvin L. ("Peck") Fox  
Edward A. ("Ted") Hosp

Attorneys for Defendant Boehringer Ingelheim  
Pharmaceuticals, Inc.

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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing has been served upon the following counsel of record to this proceeding by United States Mail, properly addressed and postage prepaid, or as indicated below, this 20th day of July, 2006:

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